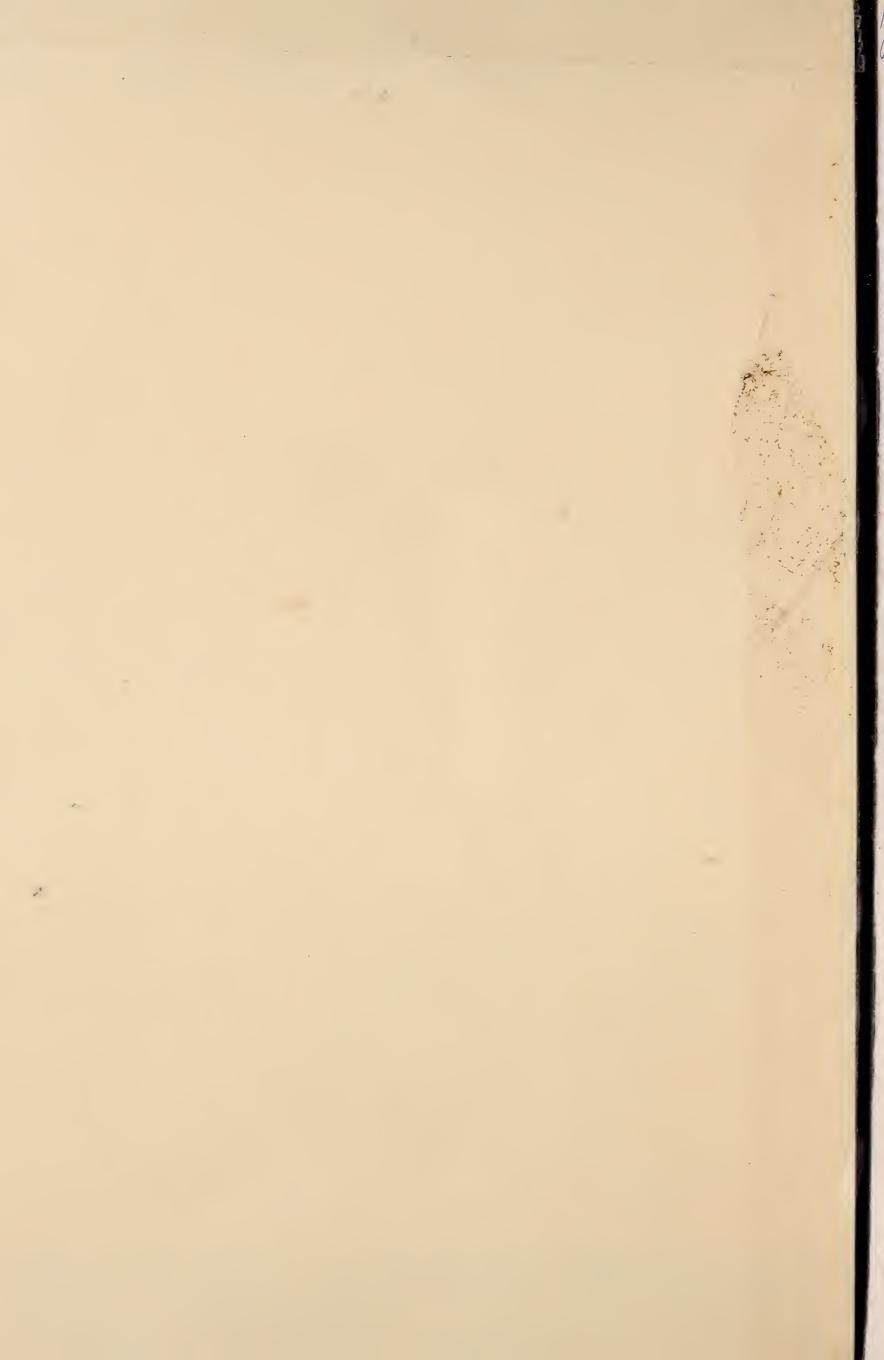
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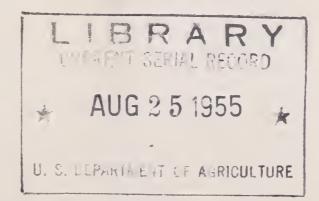
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UNITED STATES DEPARTMENT OF AGRICULTURE AGRICULTURAL RESEARCH SERVICE

SERVICE AND REGULATORY ANNOUNCEMENTS NO. 167

INTERPRETATIONS OF THE
REGULATIONS FOR THE ENFORCEMENT
OF THE FEDERAL INSECTICIDE,
FUNGICIDE, AND RODENTICIDE ACT





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UNITED STATES DEPARTMENT OF AGRICULTURE

AGRICULTURAL RESEARCH SERVICE

INTERPRETATIONS OF THE REGULATIONS FOR THE EN-FORCEMENT OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

(Title 7, Ch. III, Pt. 362 of the Code of Federal Regulations)

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INTERPRETATION AS TO APPLICABILITY OF ACT AND REGULATIONS TO OPERATIONS OF PEST CONTROL OPERATORS

INTERPRETATION NO. 1

The question has arisen as to whether the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act and the regulations promulgated thereunder are applicable to the situation in which a commercial pest control operator, as a part of his service operation, carries his own economic poisons from one State to another for application by him in his work, the material remaining in his sole and actual possession until applied. There would seem to be no question but that the substances carried by the operator are economic poisons within the literal wording of the act and the regulations. However, the purpose of the act and the regulations in requiring proper registration and labeling of the regulated substances is to protect the purchaser or user of such substances. In the situation in question, there is no purpose of sale of the substances as such or the use thereof by others. The operator is hired to control pests and as a part of his service work applies the substances. Under these circumstances it would seem that so long as the economic poisons remain in the operator's sole custody, nothing would be accomplished by requiring the registration of the substances and their proper labeling, including ingredient statements, directions for use, poison indicia, warning statements, etc. The substances are applied presumably by experts who are familiar with the nature of such substances and the risks involved. It would not appear that the activities of a commercial pest control operator, outlined above, fall within the spirit or intent of the registration and labeling provisions of the act or the regulations. Of course, any substances sold by such an operator or left by him unapplied would be subject to the act and the regulations.

While the requirements of the act and the regulations as to registration and labeling appear to have been intended primarily for the protection of purchasers and users of economic poisons, the requirements as to coloring or discoloring of economic poisons appear to be largely for the protection of the public generally, which might come in contact with the economic poisons in unmixed form either before or after use. This being so, it is considered that requirements as to coloring or discoloring are applicable to commercial pest control operations, and the interstate transportation of economic poisons in connection with such operations without complying with these requirements would consti-

tute a violation of the act.

WARNING OR CAUTION STATEMENTS FOR AGRICULTURAL DUSTS AND SPRAYS CONTAINING 2,4-DICHLOROPHENOXYACETIC ACID OR ITS SALTS OR ESTERS (2,4-D)

INTERPRETATION NO. 2

The subject matter under this heading has been superseded by that under Interpretation No. 17.

INTERPRETATION OF TERMS INCLUDED IN DEFINITION OF ECONOMIC POISON

INTERPRETATION NO. 3

(a) Economic Poison. (1) The term "economic poison" includes all substances and preparations intended for use as insecticides, fungicides (including disinfectants except those for use only on or in

living man or other animals), rodenticides and herbicides.

(2) A preparation is considered to be an economic poison if it is intended for use as an economic poison after dilution or after mixture with other substances, such as carriers or baits. These procedures are ordinarily very simple and can be done by the user of the economic poison or by a small operator with little or no special equipment. Examples of this type of economic poison include pyrethrum extract which is intended to be used as a fly spray after dilution with deodorized kerosene, lime sulfur solution intended to be diluted with water before use, calcium arsenate which may be mixed with hydrated lime before being applied as a dust, alpha naphthyl thiourea (antu) which may be mixed with a bait for use against brown rats, and numerous others.

(b) Insecticide. The term "insecticide" includes any preparation intended for use in the control of insects including closely allied classes such as spiders, mites, ticks, centipedes and wood lice. It includes not only those preparations which kill or destroy insects, but also those which repel insects—that is, drive them away. Typical examples of insecticides are those for the control of insects infesting plants, insects infesting soil, and insects infesting stored products such as grain, feeds, other foods, tobacco, or woolens; for killing or repelling insects attacking man, including mosquitoes, flies, lice, chiggers and scabies; for killing or repelling any insects attacking animals, including cattle grubs, mange mites, and bots; and for the control of insects which attack wood or other structural materials. Products intended solely for use against snails, slugs, earthworms, nemas, and worms infesting animals are not insecticides since these animals are not insects within the meaning of the law and they have not been de-

clared to be pests.

(c) Fungicide. (1) The term "fungicide" includes any product intended for the killing or control of any fungi except those on or in bodies of living man or other animals. The term "fungi" includes all such organisms as rusts, smuts, mildews, molds, yeasts and bacteria with the exception as already indicated of those on or in living man or other animals. Typical examples of fungicides are preparations intended to protect plants against fungous diseases; to treat seed for the destruction of fungous diseases; for disinfecting premises to prevent the spread from such premises of diseases of man or animals; for disinfecting dishes, food-handling equipment, surgical instruments, barber and beauty shop utensils, and other inanimate surfaces or objects; for reducing bacteria count in water supplies as by the use of chlorine (not including flocculating materials which are intended to remove bacteria mechanically); to act as preservatives by preventing the growth of bacteria, yeasts, molds, etc.; to prevent

rot or decay of wood by preventing the growth of organisms causing

rot or decay.

(2) Products intended solely for use against bacteria or other fungion or in the bodies of living man or other animals are not fungicides within the meaning of the law and are not covered by it. Also, paints which protect surfaces solely by forming an impervious coating, and not by destroying or preventing growth of bacteria and other fungi, are not considered as fungicides under the act. Paints applied to tree wounds, which act by destroying or stopping growth of fungi, and wood preservatives which may be applied by a brush treatment

are fungicides.

(d) Rodenticide. The term "rodenticide" includes all preparations intended to kill or repel rodents but does not apply to preparations for use against other vertebrate animals since no other vertebrate animal has been declared by the Secretary to be a pest. Rodents include all Rodentia such as rats, mice, rabbits, gophers, prairie dogs, and squirrels. Typical rodenticides are preparations for killing rats, mice, or squirrels, or for repelling rabbits or squirrels. The rodenticides for killing rats, mice, etc., may be used either in baits, as tracking poisons (that is, in poisons which may be taken up by the rodents' feet), in rodents' drinking water, or as fumigants. Preparations intended for use against birds, moles, dogs, wolves, and mountain lions are not rodenticides at this time, but would be rodenticides should the Secretary declare the animals named to be pests.

(e) Herbicide. The term "herbicide" includes all preparations intended for use in destroying or preventing growth of plants which grow where they are not wanted. It is not held to include preparations intended to prevent the drop of fruit, or cotton or potato defoliators.

(f) Intent. A substance or preparation is or is not an economic poison depending upon the purposes for which it is intended. Determination of intent in the marketing or distribution of the article is, therefore, highly important. This determination will depend upon the facts in the particular case which tend to show intent or lack of intent. In general, if the result which follows a certain act is that which a reasonable person would expect, it is considered to be the intended result. The intention may be either expressed or unexpressed. The distributor of the product is assumed to be an intelligent person and, except in those cases where the uses are kept secret from him, to have general information as to the purposes for which his product is being used. Some of the conditions under which a substance will be construed as being intended for use as an economic poison follow:

(1) The intent may be expressed in one or more ways, as for

example:

(i) Claims or directions for economic poison uses in the label or labeling.

(ii) Claims or recommendations for use in collateral advertising such as that in periodical publications, in advertising literature which does not accompany the article, or over the radio.

(iii) Statements either verbal or in writing by representatives of

the manufacturer, shipper, or distributor of the goods.

(2) In the absence of express statements, intent may also be shown by the circumstances surrounding the marketing of the article.

(i) When an article is used principally or only as an economic poison, it is considered to be intended as an economic poison unless there is a definite showing of intent for other purposes. Examples of products of this kind are pyrethrum powder, lead arsenate, calcium arsenate, preparations containing dichloro diphenyl trichloroethane (DDT), lime sulphur solution, bordeaux mixture, liquor cresolis

saponatus, and many others.

(ii) Many products are sold for both economic poison and non-economic poison uses. For example, a rat and mouse killer may also be recommended for use against moles, a coal-tar disinfectant may also be recommended for use as a deodorant, a sodium hypochlorite disinfectant may also bear directions for use as a bleach, a fungicidal treatment for shoes may also be recommended for treatment of the feet for athlete's foot. In all such cases, even when most of the claims are for noneconomic poison uses, the product is subject to the law. If the product is intended for one or more uses as an insecticide, fungicide, rodenticide, or herbicide, it is an economic poison and must comply in all respects with the provisions of the act, including the provision that it must not bear any false or misleading statement concerning any of its uses.

(iii) When an article has both economic poison and noneconomic poison uses, it is considered to be an economic poison if it is prepared in a special form for uses as an economic poison. Thus, sulfur ground to a very fine form and treated with a conditioning agent to make it suitable for use in dusting plants, formaldehyde paste prepared in a vessel equipped with a burner to volatilize it for fumigation, strychnine which has been impregnated into a bait for rodents and similar

materials are intended as economic poisons.

(iv) When an article has both economic poison and noneconomic poison uses, it is considered to be an economic poison if it is marketed in channels of trade where it will presumably be purchased as an economic poison. This provision is to be interpreted reasonably and in the light of market conditions in the particular places where the product is to be sold. It is not the purpose to require a product to be registered and labeled as an economic poison merely because a few persons, on their own initiative, purchase an insignificant portion of the product distributed through the particular channel of trade, for economic poison uses. On the other hand, if it is known to the distributor or is common knowledge that a considerable portion of the product in the channel of trade concerned is actually being used as an economic poison, it will be considered as being intended for use as an economic poison.

(3) Examples of circumstances which will determine intent are

as follows:

(i) Tartar emetic has been used in considerable amounts in some parts of the country to control thrips. When sold through supply houses in these sections where it will go to the agricultural trade, it is an economic poison. In other parts of the country, it has little or no economic poison use and when marketed in these sections, it would not be considered an economic poison.

(ii) Caustic soda (sodium hydroxide) is sold in large drums or in solution in tank cars for use in paper making, in the rayon industry, or in other chemical industries. When marketed in this manner, it

is not an economic poison. However, it is sometimes recommended for use as a disinfectant and when sold through channels where it is likely to be used as a disinfectant, it is an economic poison.

(iii) Stoddard solvent is used primarily as a cleaning fluid, but it has also been found to be a weed killer for use on young carrots. Where the preparation is only used for cleaning, it is not an economic poison and need not be registered. It will be considered as an economic poison only in those cases where there is reason to believe it will

be used for weed killing or some other economic poison use.

(iv) Kerosene, as such, is used to some extent for the control of bedbugs and for certain other insecticidal uses. However, the amount used is only an insignificant proportion of that marketed. Except in those cases where there is some specific indication of intent for use as an economic poison, kerosene will not be considered an economic poison.

(v) Phenol is used in large quantities in the plastic industry. When so used, it is not an economic poison. It is also marketed as a disinfectant primarily through drug houses. When sold where considerable amounts of it are likely to be used for disinfecting, it is an eco-

nomic poison.

(g) Specific Products Not Considered as Economic Poisons. The following products concerning which questions have been raised are not economic poisons within the meaning of the act:

(1) Deodorants, bleachers, and cleaners.

(2) Products intended to kill or repel moles, wolves, birds, or dogs.
(3) Disinfectants for use on or in the living body of man or other

animals.
(4) Embalming fluids.

(5) Preparations intended to prevent fouling of ships' bottoms by barnacles or other marine animals.

(6) Lime when sold for the preparation of lime-sulfur solution or bordeaux mixture.

(7) Preparation intended for use against nemas, earthworms, garden slugs or snails.

(8) Building materials which have been treated with insect repel-

lent materials to prevent their being attacked by insects.

(9) Woolens which have been treated with mothproofing materials to prevent their destruction by clothes moths.

(10) Plant hormones (except when they are intended for weed

killing or other economic poison purposes).

(h) Products Being Tested Experimentally. A product is considered not to be an economic poison and, therefore, not to be subject to the act when it is only being tested to determine its value for economic poison purposes, or its toxicity or other properties, and when the user does not expect to receive any benefit in pest control. This would include all products shipped to pharmacological laboratories to determine their toxicity to animals so as to discover what cautions or warnings are necessary, and products used on small plots of crops where the plots are grown solely to make the tests. Products intended to be used on larger scale tests, especially where the product is sold to the user, are likely to come within the provisions of the law since in these cases the user expects to obtain benefit in pest control. When the economic poison is being subjected to larger scale efficacy tests,

where the user expects to obtain benefit from its use, it will be subject

to the "permit" provision of the act.

(i) Products Which Require Further Processing. A product is not considered to be an economic poison when it is intended for economic poison use only after further processing or manufacturing such as grinding to dust form or more extensive operations. A product which requires additional manufacturing process is not considered to

be a completed product.

(j) Economic Poisons Which Are Also Drugs. The act covers all products intended for use against insects wherever they occur. Mange is commonly understood to be a disease. It occurs in both man and animals. It is, however, caused by a mite, which is an insect within the meaning of the law. Therefore, products intended to destroy the causative organisms of mange or scabies, whether in man or animals, are insecticides within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act.

To avoid any conflict in the application of this act to products also covered by the Federal Food Drug and Cosmetic Act liaison has been set up between the Plant Pest Control Branch and the Food and Drug

Administration with frequent consultations.

INTERPRETATION WITH RESPECT TO NAMES OF PRODUCTS

INTREPRETATION NO. 4

(a) Permissible Names. (1) The act does not prohibit the use of any name for an economic poison which is not false or misleading in

any particular.

(2) Names which give clear, nonmisleading information as to the composition of the product are permissible. Thus the names "standard lead arsenate," "lime sulfur solution," "pyrethrum powder and lead arsenate," "sodium salt of 2,4-D," "bordeaux mixture," "nicotine dust" and "paris green" may be used for the products mentioned. If a product contains two or more ingredients, it is permissible to name only one of the ingredients if the ingredient named is present in sufficient proportion itself to make the product effective for the purposes for which it is intended and if the name clearly indicates the presence of other constituents; or if the ingredient is present in sufficient proportion to be of value and its percentage is clearly shown in the name. Examples of acceptable names of this type are "Brown Rat Killer with Antu," "5% Antu for brown rats," or "Antu 5% for brown rats," for a preparation containing 5 percent antu; "5 percent nicotine dust" or "Dust containing nicotine" for a preparation containing 5 percent nicotine and recommended for uses where this amount of nicotine is an adequate control; "1% DDT spray" (but not "spray containing DDT") for a preparation containing DDT among other constituents but insufficient DDT to be effective in and of itself for all of the purposes for which the product is intended.

(3) If a product consists of a principal active ingredient together with other ingredients which may be either active or inert and the principal active ingredient is present in sufficient amount to be effective for all of the purposes for which the product is intended, it may bear the name of the principal active ingredient followed by the term "dust," "spray," "mixture," "insecticide," "fungicide" or similar term

in type of equal prominence, without other qualification. However, if this form of name is used, the ingredient statement following the first option and, in case of use of such terms as "insect killer," the types of pests to be controlled must appear prominently on the front panel of the label.

Examples: Nicotine dust Rotenone dust DDT spray

(b) Conditions Under Which a Name Is Considered To Be False or Misleading. (1) A descriptive or partially descriptive name may be false or misleading by reason of its giving a wrong impression of the composition of the product. This may be done in a number of ways. For example, (i) the product may consist of several ingredients but the name may specify only one of them, thus giving the impression that the product consists of only the one ingredient; (ii) the lettering used in the name of the product indicating the presence of one of the ingredients may be in large type or in a different color than the rest of the name so that it is unduly emphasized; or (iii) an ingredient mentioned in the name may be present in such a small amount that

it is of no practical value in the product.

(2) A name may also be false or misleading because it claims or implies effectiveness for the product which it does not possess. Claims may be false because the name contains a direct misstatement as, for example, "roach killer" for a product which does not kill sufficient roaches to be an adequate control for them, or "moth repellent" for a preparation which is not repellent to moths, or they may be objectionable because they are too broad. Examples of objectionable broad names when used without qualification are "Insect Killer" for a household insecticide consisting of pyrethrum extract and deodorized kerosene; "Ant Killer" for a preparation which will attract and kill only sweet-preferring ants; "Rat Killer" for a preparation dependent upon antu for its effectiveness; and "Weed Killer" for a preparation dependent upon 2,4-D for effectiveness. The false impression created by such names as these can frequently be overcome by naming the pests to be controlled, prominently and in close proximity to the name of the product on the front panel of the label, as, for example, "5% Antu Rat Killer for brown rats" or "Insect Killer for flies, mosquitoes, roaches and bedbugs," assuming, of course, that the product is effective for the pests named. In the case of products sold as "Weed Killer containing 2,4-D," "Insect Spray" or "Insect Dust," the names of the particular weeds or insects to be controlled need not be contained on the front panel of the label if they are placed prominently on the back panel, since it is believed that most users would not be misled by this procedure.

(3) A coined name may be misleading because it gives a misleading impression of the composition or the effectiveness of the product. Such names are as much in violation of the law as if the misleading impression were given by a direct statement. A name such as "Para-Camph" for a moth killer would indicate a mixture of paradichlorobenzene and camphor, the former being present in the larger amount. "Parapur" would imply straight paradichlorobenzene. The use of variations of the term "steril" in the name of a disinfectant is likely to

imply sterilization.

(c) Names Registered as Trade-Marks. In determining whether or not to register a trade-mark, the Patent Office makes no determination of its legality under the Federal Insecticide, Fungicide, and Rodenticide Act. Therefore, such registration cannot be accepted as evidence that a name is legal under the act. If a name is false or misleading, it is in violation of the act whether or not it has been registered as a trade-mark. Sometimes the misleading impression can be overcome by clearly and prominently indicating in the name that the name is only a brand name and by clearly stating the limitations of the product.

INTERPRETATION WITH RESPECT TO INGREDIENTS AND INGREDIENTS STATEMENTS

INTERPRETATION NO. 5

(a) Labels Must Bear Ingredient Statements. (1) The label of each economic poison must bear either:

(i) A statement of the name and percentage of each active ingre-

dient and the total percentage of the inert ingredients, or

(ii) A statement of the names of each of the active ingredients in the descending order of the amount of each present, followed by a statement of the names of each of the inert ingredients, if any, in the descending order of the amount of each, and the total percentage of the inert ingredients.

(2) If the economic poison is highly toxic to man, the first form of

ingredient statement must be used.

(3) In addition to one of the above forms of ingredient statement the label of an economic poison containing arsenic must state the percentages of total and water soluble arsenic, each calculated as elemental arsenic.

(4) The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the terms "inert ingredients," or the singular forms of these terms when appropriate. These terms shall be in the same size type and equally prominent. It is preferable, but not required, that these designations be set over well to the left, and that the names of the ingredients be indented.

(5) In the ingredient statement for a product which contains 100 percent of active ingredients, the statement "Inert ingredients, none"

is not required.

(6) Unless the ingredient statement is a complete analysis of the economic poison, the term "analysis" should not be used as a heading

for the ingredient statement.

(b) Definition of "Ingredient." (1) Ingredients are the simplest constituents of the economic poison which can reasonably be determined and reported. A mixture of ingredients is not to be reported as a single ingredient except in those cases where it is not practical to separate them. A solution is a mixture of ingredients, and not a single ingredient.

(2) In the case of the simpler economic poisons which consist of mixtures of readily determinable chemical compounds, the actual compounds present are the ingredients. For example, the following are ingredients of economic poisons: Lead arsenate, copper sulfate pentahydrate (in blue vitriol), copper sulfate monohydrate, tricalcium

arsenate, copper acetoarsenite (in paris green), water, ethyl alcohol, sulfur, alpha naphthyl thiourea, and sodium salt of 2,4-dichlorophenoxyacetic acid. It should be borne in mind that the compounds present in the economic poison may differ from those put into it. When copper sulfate pentahydrate, for example, is dissolved in water, the result is a solution of copper sulfate. The water of crystallization will have become merely water of solution, and will no longer be part of the active ingredient. When sodium hydroxide (lye) and fatty acids are added together in suitable proportions, the result is soap.

(3) In the case of the more complex economic poisons, it may not be practical to determine the actual chemical compounds present. In such cases, the statement of ingredients as actual compounds is not feasible, and some other method of statement which will be both practical and informative to the purchaser must be used. Examples of this type of ingredient are kerosene, tobacco other than nicotine (for the inert portion of powdered tobacco), and copper (stating the form in which it is present) in indefinite compounds such as basic copper carbonate or basic copper sulfate.

(4) If the manufacturer is in doubt as to what constituents of his economic poison are to be considered ingredients, he may furnish the Plant Pest Control Branch full information as to its formulation, the results of chemical analysis, and any other pertinent data, and the Branch will aid him insofar as possible to determine which constituents should be considered ingredients.

(c) Active Ingredients. (1) The active ingredients of an economic poison are those which are capable, in themselves, of preventing, destroying, repelling, or mitigating insects, fungi, rodents, weeds, or other pests when used in the same manner and for the same purposes as those for which the economic poison is intended. An ingredient which is antagonistic to the activity of the principal active ingredient cannot be considered active because it actually decreases the effectiveness of the economic poison.

(2) If an ingredient is present in such a small proportion that it does not add materially to the effectiveness of the product, it is misleading to name it as an active ingredient.

(3) If an economic poison is intended for two or more economic poison purposes (for example, as a combined insecticide and fungicide), each of the ingredients which is active for one or more of the intended economic poison uses shall be considered as an active ingredient.

(4) The Chief may require an ingredient to be designated as an active ingredient if, in his opinion, it sufficiently increases the effectiveness of the economic poison to warrant such action. Sesamin, which is not itself an effective insecticide, but which greatly increases the effectiveness of pyrethrins in deodorized kerosene, is considered an active ingredient in such mixtures.

(d) Inert Ingredients. All ingredients which are not "active" as defined in the preceding section are inert within the meaning of the law. This includes the following types of ingredients (except when they have economic poison effectiveness of their own): Solvents such as water; baits such as sugars, starches, meat scraps, etc.; dust carriers such as talc and clay; fillers; wetting and spreading agents; propellants in aerosol dispensers; emulsifiers; and other. The fact

that these ingredients are necessary in the practical application of the

economic poison does not make them active ingredients.

(e) Position of Ingredient Statement. (1) The ingredient statement is, in general, required to appear on that part of the immediate container of the retail package which is presented or displayed under customary conditions of purchase—that is, on the front panel. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper.

(2) If the size or form of the package makes it impractical to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear on some other panel of the label. If the package contains not more than one pound of a solid or one pint of a liquid, the ingredient statement may appear

on the side or back panel.

(3) In case the ingredient statement is unusually long, permission may be granted to place it on a side or back panel of packages contain-

ing not more than $2\frac{1}{2}$ pounds of a solid or 3 pints of a liquid.

(f) Prominence of the Ingredient Statement. (1) The ingredient statement must be placed prominently on the label and with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase. To fulfill this requirement the statement must:

(i) Run parallel with the other printed matter on the panel on

which it appears; and

(ii) Be on a clear contrasting background; and

(iii) Not be obscured or crowded—that is, it must have a reasonable amount of clear space around it and not be placed in the body of read-

ing matter; and

(iv) Be in type large enough so that it is likely to be read. It is not possible to state a minimum size of type which will be applicable to all packages. In general, the type used should be at least as large as that used for the directions or other wording in close proximity to the ingredient statement. In some cases, it may have to be larger to achieve the requisite prominence. In any case it should be large enough to be easily read by an individual with normal eyesight with-

out the aid of glasses.

(g) Names To Be Used in the Ingredient Statement. (1) It is the purpose of the act that the names used in the ingredient statement shall be as informative as possible to the persons purchasing the economic poison and other interested persons, such as official advisors as to the use of economic poisons (county agents, extension entomologists, plant pathologists, agronomists, and rodent control officials), and to physicians when necessary for the preparation of antidotes. The name used for the ingredient shall be the well-known common name, if there is such a name. If there is no common name, and the chemical name is known, it should be used when it will be properly informative. A trade-mark or trade name may not be used as the name of an ingredient except when it has become a common name.

(2) In many cases there is no well-known common name and no chemical name. In such cases, the name used for the ingredient should be as informative as possible. It may be a descriptive name, such as

derris resins or tobacco other than nicotine.

(3) In some cases where there is no common name, the chemical composition may be unknown or so complex that use of the chemical name would not be practical. In such cases, the Chief may permit the use of a new or coined name for the ingredient if this will simplify

the ingredient statement and not hide information.

(i) A new or coined name will normally refer to a single chemical compound, or at least to a definitely defined material. Its adoption usually entails discussion with interested groups, such as representatives of the chemical, entomological, medical, and plant pathological scientific groups, as well as with the manufacturers of the material. The purpose is to obtain a name which is easy to use and informative to the public. The new or coined name must not be covered by private trade-mark and must be free for general use.

(ii) Since new or coined names will not be common names when first used, they should at first be accompanied by the chemical or other descriptive name of the ingredient. As an example, if a new or coined name were adopted for a chemical which was the only active ingredient in an economic poison, the ingredient statement would be in the follow-

ing form:

1 Consists of (full name of chemical compound).

It is necessary to include the name of the compound since cases of poisoning may occur and the coined name alone will not be sufficiently

informative for the attending physician.

(h) Statement of Percentages. (1) The percentages of ingredients shall be stated in terms of weight. Statements in terms of percentage by volume or on a so-called "Weight-volume" basis do not fulfill the requirements of the law, but may be used as additional statements, if they will be informative to the purchaser and not misleading. For example, in addition to the ingredient statement in terms of percentage by weight, the label of a DDT solution in kerosene may bear a correct statement such as "Contains ___ oz. of DDT per gallon of product," the correct value to be inserted in the blank space. In many cases such a procedure is desirable.

(2) The sum of the percentages of the active and the inert ingredi-

ents shall be 100.

(3) Sliding scale forms of percentage statements, such as "22-25",

shall not be used.

(i) Accuracy of Statement of Percentages. (1) The percentages given for the active and inert ingredients should be as nearly correct as possible in good manufacturing practice. In case there is a small unavoidable variation in the percentage of the active ingredients in different batches of an economic poison, the value stated shall be the lowest percentage of the active ingredient which may be present, so that the purchaser can always depend upon receiving a product of at least the strength promised him. However, the variation above the value stated should not be unreasonably large. Actual figures for permissible variation will depend upon the facts in the particular

Percent

case. Percentages should not be stated to a greater degree of accuracy

than the facts warrant.

Active ingredient:

(2) Inert impurities which are present in substantial amounts in active ingredients, are to be considered as inert ingredients in the ingredient statement. If the impurities are present in less than substantial amounts and their presence does not reduce the effectiveness of the product, their presence may be neglected. What constitutes substantial amounts will depend upon the special circumstances in the particular case, but, as a general rule, if the total proportion of impurities in the product is less than one percent and if they do not substantially reduce the effectiveness of the product, they may be neglected. Thus a technical sodium fluoride containing 95 percent of actual sodium fluoride and 5 percent of sodium chloride, sodium sulfate, and sodium carbonate would be required to declare the 5 percent of inert ingredients but a boric acid containing 99.1 percent of actual boric acid could be considered as consisting entirely of boric acid.

(j) Economic Poisons Which Deteriorate. (1) Economic poisons must be effective for the purposes intended and have the proportions of active ingredients claimed as long as they are subject to the act.

- (2) If the product is one which loses strength on standing, this should be taken into account in preparing the ingredient statement and marketing the product. In such cases, the product should be marketed in such a way that it will all be used before appreciable deterioration has taken place, or allowance should be made for deterioration of the product in preparing the ingredient statement. For example, if an economic poison will lose 10 percent of its strength in six months, its ingredient statement may show the strength that it will have at the end of six months, and then it may be marketed so that it will all be used up by that time. However, it must be effective for the purposes claimed even at the lower strength.
- (3) If the product is one which is intended to attract insects or rodents and will lose its attractiveness, after a time, it should not be marketed after that time. A prominent statement, "Not to be used after _____," is allowable.

 (Date)

(k) Acceptable Forms of Ingredient Statement. Some acceptable forms of ingredient statement follow: (1) For commercial calcium arsenate and other calcium compounds:

Tricalcium arsenateInert ingredients	
Total	
Total arsenic calculated as elemental arsenic arsenic calculated as elemental arsenic not more the	
(2) For bordeaux mixture.	
Active ingredient: Copper (in bordeaux mixture) Inert ingredients	
Total	

(3) For fly spray containing pyrethrum extract and deodorized kerosene:
Active ingredients: Pyrethrins Petroleum distillate
or
Active ingredients 100
Petroleum distillate. Pyrethrins.
(4) For pine oil disinfectant made of pine oil, soap, and water:
Active ingredients: Pine oil
Inert ingredients
Total
A chima in and disarta :
Active ingredients: Pine oil
SoapInert ingredient, water
Total 100
(5) For brown rat bait consisting of alpha naphthyl thiourea (Antu) and bait materials:
Active ingredient: Alpha naphthyl thiourea
Total
(6) For a weed killer containing the sodium salt of 2,4-dichlorophenoxyacetic acid (2,4-D):
Active ingredient: Sodium salt of 2,4-dichlorophenoxyacetic acid ¹
Inert ingredients
Total100
¹ Equivalent to 2,4-dichlorophenoxyacetic acid percent.
The correct values for the percentages should in each case be inserted in the blank spaces.
INTERPRETATION WITH RESPECT TO STATEMENT OF NET CONTENTS
INTERPRETATION NO. 6
(a) Requirement of the Act. The act requires that the label of each economic poison bear a statement of the net weight or measure of the contents.
(b) Terms of Weight or Measure. (1) If there are terms of weight or measure in general use for a particular economic poison which will give accurate information to users as to the quantity of content, such terms shall be used on the label

(2) When there is no general usage in the trade with respect to the terms of weight or measure of a particular economic poison, the con-

tent must be stated in terms of liquid measure if the product is a liquid, and in terms of weight if it is a solid, semisolid, viscous, or a mixture

of liquid and solid.

(i) Liquids include all substances which flow freely like water and thus can be readily measured. Oils of low viscosity such as kerosene, cresote oil and pine oil are liquids. Emulsions with low viscosity are liquids. but emulsions of high viscosity such as mayonnaise, or viscous tars are not liquids within the meaning of this definition.

(ii) The terms solid, semisolid, viscous, and mixture of liquid and

solid include all products other than liquids.

(3) Statements of liquid measure must be in terms of the United States gallon, quart, pint, and fluid ounce at 68° F.; statements of

weight must be in terms of avoirdupois pound and ounce.

(4) Some liquid economic poisons are usually sold by weight. Examples are nicotine sulfate solution containing 40% of nicotine and U. S. P. formaldehyde solution. The content of these liquid eco-

nomic poisons must be stated in terms of weight.

(5) In a few cases economic poisons are sold in gelatine capsules and the contents of such capsules stated in terms of fluid drams. Where such usage has been general, the net content must be given in terms of the number of capsules each containing a stated number of fluid drams.

(6) Some disinfectants are made up in tablet form. When so prepared, objection will not be raised to giving the number of tablets and

the weight of each.

- (c) Units of Weight or Measure. Statements of net content must be in terms of the largest unit present, but in the case of added fractions of the largest unit, the fractional portion may be expressed in terms of a smaller unit. Thus, 3½ pounds may be stated as "3½ pounds" or "3 pounds, 8 ounces"; 5½ gallons may be stated as "5½ gallons" or "5 gallons, 2 quarts"; 3¾ quarts may be stated as "3¾ quarts," "3 quarts, 1½ pints," or "3 quarts, 1 pint, 8 fl. oz." It is not permissible to state net contents such as 128 fluid ounces, 32 fluid ounces, 6 pints, 8 quarts, or 24 ounces since in each case the statement is not in terms of the largest unit present.
- (d) Permissible Variations. (1) If the contents are stated as a minimum quantity, the package must contain at least the quantity claimed. No variation below this quantity is permitted and any variation above the contents stated must not be unreasonably large.

(2) The net content is considered to be the average net content unless stated as a minimum quantity. Where average net content is

used:

(i) The average content of the packages in any shipment must not fall below the quantity stated and variation above the quantity stated is permitted only to the extent that it represents deviations unavoidable in good packing practice.

(ii). There must be no unreasonable variation from the average in

the content of any package.

(e) Allowance for Loss. A statement of net content "when-packed" does not comply with the requirements of the act. The statement must be such that it will be correct as long as the economic poison is subject to the law. Thus, if a product such as borax may lose weight

by drying out when stored in paper bags, it must be packed and labeled in such a way that the statement of net content will be correct when

the product is purchased.

(f) Location and Prominence of Net Content Statement. (1) The net content statement must appear on the label of the container. It is not required to appear on the front panel of the label but it must be prominently placed with such conspicuousness as to render it likely to be read by the purchaser under customary conditions of purchase and use. In the case of drums or bags the net content may be plainly and conspicuously stenciled on the drum or bag. If a single label is printed for use on several different sizes of containers, the net content may be plainly inserted on each label with a rubber stamp or by any other method which gives the information clearly.

(2) When the retail package contains smaller unit packets as, for example, for single doses, the net contents must appear on the retail package but need not appear on the individual packets. Thus, if a rodenticide is made up into individual baits enclosed in cellophane, and these baits are packed in a retail package, the net contents should be shown on the retail container but need not be shown on the individual baits. However, if the individual baits are at any time marketed separately, they must bear the net content statement as well

as other required information.

INTERPRETATION OF REQUIREMENTS WITH RESPECT TO DIRECTIONS FOR USE

INTERPRETATION NO. 7

(a) Requirement of the Act. The act requires that the labeling accompanying each economic poison must contain directions for use which are necessary and, if complied with, adequate for the protection

of the public.

(b) When Directions Are Required. Directions for use are required whenever they are necessary for the protection of the public. The public includes not only users of economic poisons, but also those who handle them or may be affected by their use, handling, or storage. Directions for use are considered necessary in the case of most small retail containers which go into the hands of users, and in the case of larger containers with the following exceptions:

(1) Directions may be omitted where the economic poison is sold in containers of 50 pounds or more of a solid or 20 gallons or more

of a liquid, Provided:

(i) The economic poison is a well-known substance or mixture of substances for economic poison purposes and is intended only for the use to which it is ordinarily applied, and

(ii) Is not a proprietary article—that is, one sold under a trade

name, and

(iii) Bears an ingredient statement giving the names and percent-

ages of each of the active ingredients.

Examples of such products are 100-pound drums of naphthalene to be used against clothes moths, 50-pound bags of sulfur intended for spraying fruit trees, and 200-pound drums of calcium arsenate for dusting cotton. It may be presumed that purchasers of economic poisons in large amounts, such as those indicated, will be familiar with their uses and that no directions will be necessary.

(2) Directions may be omitted if the economic poison is to be used by manufacturers of products other than economic poisons in their regular manufacturing processes, *Provided*:

(i) Option 1 for the ingredient statement is followed, and

(ii) The label clearly shows that the product is intended for use only

in manufacturing processes.

When a manufacturing process requires use of an antiseptic or disinfectant, the manufacturer may have to determine by tests with his own particular process how the antiseptic or disinfectant should be applied. Similar considerations may apply, for example, to the application of the mothproofing preparation in woolen finishing processes.

(3) Directions may be omitted if the economic poison is sold only to physicians or veterinarians, provided option 1 for the ingredient

statement is followed.

(4) Directions may be omitted if the economic poison will be dispensed only on prescription of a physician or veterinarian, *Provided*:

(i) Option 1 for the ingredient statement is followed, or

(ii) The proportion of each of the active ingredients is clearly stated in addition to the ingredient statement as specified in option 2.

(5) Directions may be omitted if the economic poison is sold to distributors for dilution or mixing with carriers to prepare economic poisons for sale to the public, *Provided*:

(i) Option 1 for the ingredient statement is followed, and

(ii) The economic poison is a well-known substance or mixture of

substances, and

(iii) There is readily available general knowledge of the composition, methods of use, and effectiveness of the product for economic poison purposes.

For example, the usual 20 to 1 pyrethrum extract is sold to mixers to prepare finished fly sprays. Its uses are well recognized and when its label bears the ingredient statement giving the percentages of pyrethrins and petroleum distillate, the mixer should know how to prepare his product without further instructions. On the other hand, if the concentrate has a new or unusual composition and if its properties are not well-known, it will be necessary that the mixer be furnished directions for use on the labeling.

(c) Where Directions Shall Appear. The directions, when required, shall appear on the labeling accompanying the article. The term "labeling" includes the actual label on the retail package and all circulars or leaflets accompanying it. The directions for use may, therefore, appear either on the label or on a circular or leaflet accom-

panying the economic poison.

- (1) If the directions are placed on the label, they may be on the front, side or back panel, and they must appear with such conspicuousness and in such terms as to make them likely to be read and understood. Directions printed on the back of a front panel label of a bottle, so that they must be read through the bottle and its contents, are not ordinarily sufficiently conspicuous to fulfill this requirement of the law.
- (2) If the directions are on a circular or leaflet, this circular or leaflet must accompany each retail package so that each purchaser will receive a copy of it. The circular or leaflet should be enclosed with, or securely attached to the retail container. Circulars or leaf-

lets which are insecurely attached, as for example, by means of a rubber band, are likely to be lost. If the economic poison is packed in a bottle or other container enclosed in a wrapper or carton, the circular may be placed in the wrapper or carton with the immediate container of the economic poison. If the economic poison is a dry powder packed in a bag or other container, the circular may be placed in the top of the bag or other container, where it will come to the purchaser's attention when he first opens the container. In this case, it is preferable to place on the label a statement such as "See directions on enclosed circular."

(d) Adequacy of Directions. (1) The directions for use must be sufficient to protect the public. This means that the purchaser, if he follows them, will obtain the results promised him in the labeling, or which he may properly expect to obtain by use of the product, without injury to person or property. It does not mean that the directions need be exhaustive in every case. Some of the common economic poisons are intended for use against a large number of insects, plant diseases or weeds. Frequently the methods of control in different parts of the country vary and they may vary in a single place from year to year, depending on weather conditions. It would be manifestly impractical to include all directions for use on the labeling.

(2) The need for detailed directions for use will be greater in the case of the small user who is not in position to be well versed in the use of economic poisons than it will in the case of a large user who is likely to make a study of the properties of economic poisons and also to rely on local agricultural authorities for advice. The need is also greater in the case of new economic poisons or those of unusual com-

position than it is in the case of older, standardized materials.

(3) The following general considerations apply:

(i) Directions for use of economic poisons which are likely to be applied by householders or small gardeners, cattle raisers, etc., should be sufficiently detailed to give full information on usage. They should include methods of application, time of application, dilutions, if any, and when necessary they should provide for repeated treatments. The directions for use should be consistent with the caution or warning statement on the label.

(ii) Directions for use of well-known, standardized economic poisons which will be applied by professional pest control operators, may be more general in nature, giving instructions for use for some of the more important purposes and, when desirable, referring to local agri-

cultural authorities for further information.

(iii) Directions for use of new or unusual economic poisons should be given in full detail so that the purchaser will know how the product is to be used. He will ordinarily have no other source of advice on the

use of the product.

(e) Applicability of Directions. Directions for use in the labeling of economic poisons are considered to apply in all parts of the country in which the product is marketed unless the labeling makes a direct statement to the contrary. It has been found that some pests are more easily controlled in certain parts of the country than in others. If an economic poison has a Nation-wide distribution, the di-

rections for use should apply to all parts of the Nation. However, if work by the State experiment stations in certain sections of the country shows, for example, that a weaker dilution of the product will be effective against a certain insect in those particular sections than is required in other sections, objection is not raised to recommendation of the weaker dilution in the particular sections involved or to a reference to agricultural authorities in those sections for information as to usage there. If the product is marketed only in the sections where the weaker dilution has been found effective, the weaker dilution may be recommended without reference to the dilution required elsewhere. However, a statement to that effect should accompany the application for registration.

(f) Clarity of Directions. The directions for use should be stated in such terms and with such clearness that they will be readily understood by the purchaser. It should be clearly indicated which directions are applicable to the control of each pest which the product is

intended to control.

(g) Broad Claims. The directions for use must not contain unjustified broad claims. Such claims, which are not acceptable in most

cases, include the following:

(1) Broad references to insects, vermin, or a list of insects followed by the abbreviation "etc." which are likely to be interpreted as implying that the product will kill or control any or all insects or vermin.

(2) Claims for extermination of insects. (Objection is not raised to claims to kill or control particular kinds of insects if the product will give a reasonable control of such insects under the conditions of use.)

(3) Claims for sterilization when the product will not kill resistant

spores under the specified conditions of use.

(4) General claims for the "control of plant diseases" or a list of plant diseases followed by the abbreviation "etc." which will give the impression that the product will protect against any or all plant diseases. (Objection is not raised to naming the specific plant diseases against which the product will furnish protection when used as directed.)

(5) Broad claims indicating killing or control of all weeds unless the product will kill or control all weeds under the specified conditions

of use.

(6) Broad claims for use against rats or rodents if the preparation

is not effective against all rats or rodents.

- (7) Claims implying effectiveness of the economic poison under all conditions of use if it is not effective under all such conditions. When a product is not effective under certain conditions, as for example, in the presence of dirt, at low temperatures, or in the presence of other chemicals, the directions should make it clear that such conditions are to be avoided.
- (h) Responsibility for Claims. The shipper or guarantor of an economic poison is responsible for all claims made for it, including the directions for use. He should give only such directions as have been shown, when followed, to give an effective control of the pests involved without injury to persons or desired plants or animals.

INTERPRETATION WITH RESPECT TO REGISTRATION REQUIREMENTS

INTERPRETATION NO. 8

(a) Products Which Must Be Registered. (1) Registration is required for all economic poisons that are distributed, sold, or offered for sale in the District of Columbia or the territories, shipped or delivered for shipment in interstate commerce, exported, or imported from abroad, except economic poisons which are intended solely for experimental use. (These, however, may be subject to the permit requirements of the law.)

(2) Custom mixes (special mixtures of economic poisons prepared on the order of and according to the specifications of the purchaser) are subject to the act and must be registered. When rush shipment of such mixtures is required, special attention will be given to expediting the registration. When requested, telegraphic notification

of registration at the expense of the registrant will be given.

(b) Products for Which Registration Is Not Required. (1) Economic poisons which are made and used in the same State without the same State with the same State with the same State with the same State without the same State with the same S

Economic poisons which are made and used in the same State without entering interstate commerce need not be registered under the act since they are not subject thereto. However, registration will not be denied them since it is possible they may be shipped out of the State.

(2) Economic poisons which are delivered for shipment to any foreign country need not be registered when they are prepared or packed in accordance with the specifications or directions of the foreign purchaser.

(3) Registration will not be issued for devices or other products

which are not economic poisons.

(c) Who May Register an Economic Poison. (1) Any manufacturer, packer, seller, distributor, or shipper of an economic poison

may register it.

(2) If the manufacturer of an economic poison ships it in interstate or foreign commerce or distributes it in the District of Columbia or the territories, he will normally register it himself since it must be registered before such shipment or distribution. This is true whether the manufacturer ships it under his own label or under a label bearing the distributor's name.

(3) If the manufacturer sells to a distributor in the same State, the manufacturer may or may not register the product, but if he has not, registration by the distributor will be required before the product

is shipped in interstate commerce.

(4) If a distributor has an economic poison made for him by two or more manufacturers following exactly the same formula and labeled with identical labels which bear his name as distributor but make no reference to the actual manufacturer, the distributor may register the product, obtaining a single registration to cover the material from all sources of manufacture. On the other hand, each manufacturer may register the product which he furnishes to the distributor, but in this case the manufacturer can register his own product only and it will be necessary for each manufacturer to have a separate registration.

(d) The Effect of Registration. (1) Registration is a device to bring the economic poison to the attention of the Department of Agriculture and to furnish an opportunity to correct obvious faults in

labeling. It does not place the responsibility for correct labeling upon the Department though the Department does advise relative to revision of labeling, on the basis of available information. The shipper of the goods or the guarantor is responsible for the compliance of his labeling with legal requirements. Before placing the article on the market, he should have it thoroughly tested by experimentors competent to judge its effectiveness and make only such claims as are justified by the results of their tests. If it is likely to cause injury to human beings, or desirable plants or animals, its limitations from these standpoints should be determined and adequate cautions placed on the label. Determination should be made as to whether it is highly toxic within the meaning of the act and regulations and, if so, the label must bear the statements required with respect to highly toxic products. It is the purpose of the act to protect the public before injury occurs rather than to subject the public to the dangers of experimentation and take action only after injury has occurred.

(2) Registration is not to be understood as indicating the Department of Agriculture's approval or recommendation of the economic

poison.

(3) Federal registration does not remove the requirements for state

registration in those States which require registration.

(4) When the economic poison has been registered, no further registration under the act is required if the product is in the manufacturer's or registrant's original unbroken immediate container, and if the claims made for it and the directions for its use do not differ in substance from the representations made in connection with the registration.

(e) Multiple Products. A single registration applies only to a single economic poison, that is, to a product having the same composition, usually manufactured by the same person, and the labeling of which is identical with and bears the same claims as those covered by the registration. If a single registration is to cover the same product sold under other trade names and bearing the names and addresses of the distributors, statements showing such other names and labels shall be filed with the Plant Pest Control Branch. Thus, when a manufacturer prepares an economic poison under a stock label which does not bear his name but on which he prints names of the product and names and addresses of distributors, who obtain the product from him, the manufacturer may register the product under his name and file an additional statement showing the trade names under which the product will be sold and the names and addresses which will appear on the label. These additional statements may be filed at any time before the goods become subject to the law.

(f) Procedure for Registration. (1) Applications for registration should be sent to the Plant Pest Control Branch, Agricultural Research Service, United States Department of Agriculture, Washington 25, D. C. No fee is required. Application forms may be obtained from the Plant Pest Control Branch by request. Applications should be submitted as far in advance as possible and at least 30 days before it is desired that the registration take effect. In special cases, the Department will try to issue registration in less than 30 days, but dependence should not be placed on obtaining registration

in a shorter period except for real emergencies.

(2) As many products may be submitted for registration as desired with one application form. If there is not room on the form to name all of the products, their names may be continued on a separate plain sheet of paper attached to it.

(3) The blank spaces on the form should be filled in and the form signed by the proposed registrant or, if the registrant is a firm, by a

responsible officer.

(4) With the filled in application for registration there should be submitted two "data sheets" for each product which it is desired to register. The "data sheet" should be \$\frac{8}{2}\$ inches by 11 inches in size. A sheet of heavy typewriter paper is satisfactory. On each data sheet should be clearly stated the name of the product, the name and address of the registrant and, if it does not appear on the label, a statement giving the name and percentage of each active ingredient in the product and any pertinent information about the inert ingredients. each data sheet there should be attached a specimen of the label for the product and specimens of any leaflets, circulars, or other advertising material accompanying the product. If the same label, except for statement of net contents, is used for several sizes of the product, information as to the different sizes should be given and the label for only the smallest size need be submitted. All labels bearing different claims should be submitted. Before attaching the labels and other material to the "data sheet", the applicant should make sure that they include the required information which is as follows:

(i) The name and address of the manufacturer, registrant, or person

for whom manufactured,

(ii) The name under which the product is sold,

(iii) The ingredient statement,

(iv) The net weight or measure of content,

(v) Any caution or warning statement which may be necessary and, if complied with, will be adequate to prevent injury to living man and other vertebrate animals, and useful vegetation and invertebrate animals,

(vi) In the case of highly toxic materials, the word "poison" in red,

the skull and crossbones and the antidote statement.

On the label, or on circulars, etc., accompanying the economic poison: Adequate directions for use when necessary for the proper use of the product

(5) If the proposed registrant has doubt as to the legality of his labeling or proposed corections for it, he may first submit a rough draft form for comment. After he has received the comment, he may revise and print the labeling and submit it in duplicate for registration.

(6) If the product is being recommended for any uses, or if any claims are being made for it, other than those on the labeling submitted, these should be shown on the data sheet. It is not desired, however, that the complete script of radio broadcasts, periodical advertising and other advertising material which does not accompany the economic poison be submitted.

(7) When the application is received in the Plant Pest Control Branch, it is examined to determine whether the composition of the product appears to be such as to warrant the proposed claims for it and whether the product, its labeling, and other material submitted

appear to comply with the requirements of the act.

(8) If the information submitted is not sufficient to furnish a basis for action, the applicant may be asked to furnish additional information such as the complete formula for the product and a full description of the tests upon which the claims for the product are based. If the article or its labeling does not appear to comply with legal requirements, the applicant is notified wherein it fails to comply and given an opportunity to make corrections.

(g) Effective Period of Registration. (1) The registration becomes effective on the date that the notice of registration is issued.

(2) A registration extends for five years unless canceled for cause or at the request of the registrant.

(3) The Department can, at any time, cancel a registration and issue a registration under protest, if such action is found necessary to pro-

tect the public.

(4) The Department can cancel the registration of an economic poison at the end of five years following the registration or at the end of any five-year period thereafter, unless the registrant, prior to the expiration of the five-year period, requests that such registration be continued in effect.

(5) A registration will be cancelled at any time on request of the

registrant.

(h) Changes in Labeling or Formulas. (1) If changes in substance in the labeling of a registered product or changes in its formula are to be made, a statement of the contemplated changes must be submitted to the Department in advance so that an amended registration or new registration may be issued, if such registration is justified.

(2) The statement should show or describe the exact changes to be made, describe any tests which justify the changes, and state the

proposed effective date of the changes.

- (3) The material submitted will be considered in the same manner as is an original submission. If new or amended registration appears justified, notification to that effect will be sent the registrant. Among reasons for which the new or amended registrations under the same name may be refused would be a reduction in strength or effectiveness of the product which would make it misleading to sell the new material under the old name.
- (4) After the effective date of the new or amended registration the product shall be marketed only under the new claims or the new formula except that, upon request, a reasonable period of time may be allowed for the disposal of properly labeled old stocks. If the registrant desires to avail himself of this privilege, he should notify the Plant Pest Control Branch at the time of change of registration how much stock he has and when he expects it will be used up. Consideration will then be given to permitting its disposal.

(i) Registration Under Protest. (1) If upon receipt of a notice that his economic poison does not appear to warrant the claims made for it or that the article or its labeling does not appear to comply with the proviisons of the act, the proposed registrant insists that corrections are unnecessary and requests in writing that it be registered as submitted, the economic poison shall be registered under protest. The notice of registration under protest will be accompanied by a warning in writing of the apparent failure to comply with the law.

(2) In the case of conviction for an offense concerning which he has been warned in connection with the issuance of a registration under protest, the act provides that the registrant shall be fined not more than \$1,000 or imprisoned for not more than one year, or both fined and imprisoned, and the registration of the article shall terminate.

(3) Registration under protest should only occur when there is serious disagreement between the registrant and Department officials concerning the efficacy of, or labeling required for, an economic poison. Disagreements may in some cases be due to misunderstandings as to requirements. When they arise, it is the purpose of the Department to cooperate with the proposed registrant in an attempt to clear them up. It appears desirable that registration under protest be requested and issued only as a last resort.

INTERPRETATION WITH RESPECT TO ADVERTISING WHICH DOES NOT ACCOMPANY AN ECONOMIC POISON

INTERPRETATION NO. 9

(a) Requirement of the Act. Section 3 (a) of the act prohibits shipment or distribution of an economic poison if any of the claims made for it or any of the directions for its use differ in substance from the representations made in connection with its registration. It has been held that this includes any representations made by the manufacturer or registrant anywhere and by any means, including periodi-

cal and radio advertising.

(b) Claims Made in Advertising. Section 4a (3) of the act provides that the applicant for registration shall file a statement of all claims to be made for the economic poison including the directions for use. All claims for the economic poison or directions for its use, regardless of where made, must be filed. It is not required, nor is it desired, that all radio script, periodical advertising, etc., be submitted to the Department, but claims made over the radio or in periodicals, etc., which differ in substance from those made in the labeling, must be filed.

(c) Cooperation With Federal Trade Commission. Advertising in periodicals or over the radio is also subject to the laws enforced by the Federal Trade Commission. It will be the policy to cooperate with the Federal Trade Commission to insure that the Federal Insecticide, Fungicide, and Rodenticide Act will be administered in a manner to result in reducing to the absolute minimum any possibility of conflict with, or overlapping of the administration of, acts administered by the Federal Trade Commission. In furtherance of this policy there has been established a liaison, which is now in operation, for constant cooperation and coordination between the Federal Trade Commission and the Department of Agriculture in the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Trade Commission Act as they apply to economic poisons. In general, the policy will be for advertising, other than labeling, to be handled as in the past by the Federal Trade Commission. In the application of the above policy it is to be understood, however, that both agencies reserve the right to the full use of their respective powers when such use is necessary to protect the public interest.

INTERPRETATION WITH RESPECT TO LABELS FOR LARGE CONTAINERS

INTERPRETATION NO. 10

(a) Requirement of the Act. The act requires labels on all containers of economic poisons which come within the scope of the act. It makes no exemption in the case of large containers such as tank cars, tank trucks, or drums. Therefore, all such containers must be labeled.

(b) Where Label Must Appear. (1) In the case of tank cars, the label may be attached to the panel borne by such cars for the purpose of attaching notices, or it may be placed directly on any

conspicuous portion of the tank.

(2) In the case of tank trucks, a label attached to the tank would be technical compliance with the act. However, if a tank truck is used merely to deliver the economic poison to the user and the truck does not remain in the users' hands, a label attached to the tank would not be informative to him. In such cases it is considered permissible under the act to attach the label to the delivery receipt which is carried by the driver of the truck and left with the purchaser at the time of delivery of the goods.

(3) In the case of drums, the label may be a printed label attached to the drum or it may be stenciled on the drum. In either case it must

be one which can be easily read.

(c) What Must Appear on the Label. The following information must appear on the label:

(1) The name of the product. This must be the name under which it is registered with the United States Department of Agriculture.

(2) The name and address of the manufacturer, registrant, or person for whom manufactured.

(i) If the name is other than that of the manufacturer, the label

should indicate this fact.

(ii) If the name is not that of the registrant, it must be the name of some other person or firm which has been added by a supplemental registration statement under the provisions of section 4a of the act.

(3) The net contents of the container, or in the case of a label attached to a delivery receipt of tank truck delivery, the net amount

delivered.

(4) The ingredient statement.

(5) Any warning or caution statement which may be necessary to prevent injury to living man and other vertebrate animals, useful vegetation, and useful invertebrate animals. This statement is particularly important on large containers, since leakage may occur and result in injury to persons or property unless they are warned to take adequate precautions.

(6) In the case of an economic poison highly toxic to man, the skull and crossbones, the word "poison" prominently in red, and an antidote

statement.

(d) Directions for Use. (1) Ordinarily large containers will be sold only to large users who are in better position to know how the economic poison is to be used than is the smaller user. Therefore, in the case of common materials such as creosote oil, lime sulfur solu-

tion, naphthalene, and Stoddard solvent, where the composition is clearly indicated on the label, it will not be necessary that any directions for use be given on the label or labeling of tank cars, tank trucks, 50-gallon or larger drums, or 200-pound or larger barrels of the economic poisons.

(2) In the case of products whose full composition is not shown by

the label, directions for use must accompany the product.

(e) Acceptable Types of Labeling. (1) For creosote oil, free of water or free carbon.

Creosote Oil

ACTIVE INGREDIENT 100%

John Doe and Company New York, N. Y.

Net contents____gallons

CAUTION: Avoid prolonged or repeated contact with the skin or breathing of the vapors.

(2) For naphthalene flakes in a 200-pound barrel.

Naphthalene Active Ingredient 100%

John Doe and Company New York, N. Y.

Net weight 200 lbs.

INTERPRETATION WITH RESPECT TO THE GUARANTY OF AN ECONOMIC POISON

INTERPRETATION NO. 11

(a) Purpose of the Guaranty. (1) The manufacturer of an economic poison is presumed to know the composition of his product and he will ordinarily be the one who registers it with the Department of Agriculture. He will, therefore, be in position to determine

whether or not its shipment or distribution is legal.

(2) The distributor who purchases it from him will not be in a position to determine its composition except as he has it analyzed in a chemical laboratory and he will not know, except as his supplier may inform him, whether the product is registered, and what representations were made in connection with the registration. It will, therefore, be difficult for him to determine whether or not its shipment

or distribution is legal.

(3) In order that the distributor may protect himself the act specifies that the penalties provided for violations of section 3a shall not apply to any person who establishes a guaranty, signed by and containing the name and address of the registrant or person residing in the United States from whom he purchased and received in good faith the article in the same unbroken package, to the effect that the article was lawfully registered at the time of sale and delivery and that it complies with the other requirements of the act, giving the name of the act in full. When the distributor holds such a guaranty, the guarantor is responsible for any violation involved in the shipment of the goods. However, the distributor, to avoid responsibility, must

be able definitely to show that the economic poison in question is covered by a specific guaranty.

(b) Who May Give Guaranty. A guaranty may be given by any manufacturer, distributor, wholesaler, or any other person residing in the United States, who sells an economic poison to anyone else.

(c) Scope and Form of Guaranty. A guaranty may be either limited to a specific shipment or it may be general and continuing in nature. The following forms of guaranty are suggested:

(1) Limited form for use on invoice or bill of sale.

Name of guarantor herein listed are lawfully registered with the U.S. Secretary of Agriculture and comply with all requirements of the Federal Insecticide, Fungicide, and Rodenticide Act.

Signature and post office address of guarantor

Date

(2) General and continuing form.

The economic poisons comprising each shipment or other delivery hereafter made by ______ to or on the order of Name of guarantor

Name and address of person receiving guarantee are hereby guaranteed to be lawfully registered with the U. S. Secretary of Agriculture and to comply with all requirements of the Federal Insecticide, Fungicide, and Rodenticide Act, as of the date of such shipment or delivery.

Signature and post office address of guarantor

Date

(3) In some cases an invoice may cover shipment of both economic poisons covered by permit for experimental use and registered economic poisons. The guaranty cannot apply to the economic poisons shipped under permit. Therefore, the above forms of guaranty must be modified to be applicable to such procedure. It is suggested that in such cases the name of the experimental economic poison as shown on the invoice or bill of sale be immediately followed by the word "Experimental." Then the first form of guaranty should be changed to read:

hereby guarantees that the economic poisons Name of guarantor herein listed (except such as are designated "experimental") are lawfully registered with the Secretary of Agriculture and that they comply with all requirements of the Federal Insecticide, Fungicide, and Rodenticide Act.

Signature and post office address of guarantor

Date

A similar change should be made in the second form of guaranty.

(d) Reference to Guaranty. No reference to the guaranty may be made on the label or in the labeling of the product since such reference would be likely to give the purchaser an unwarranted sense of security.

(e) Limitation of Guaranty. The guaranty applies only so long as the economic poison remains unchanged in the manufacturer's or

registrant's unbroken immediate container bearing his label. It expires when the immediate package is opened, when the material is repacked or relabeled, or when it has been otherwise changed so as to be in violation of the law after shipment or delivery by the person giving the guaranty. For example, a product may deteriorate when stored for any considerable length of time. It may have been in strict compliance with the law when shipped by the guarantor but a year later, when shipped by the distributor, it may have deteriorated and become worthless. In this case, the guaranty would not apply to the shipment a year later.

INTERPRETATION WITH RESPECT TO THE ANALYZING AND TESTING OF ECONOMIC POISONS

INTERPRETATION NO. 12

Analyzing and Testing of Economic Poisons; Functions of the Department. Insofar as the Federal Insecticide, Fungicide, and Rodenticide Act is concerned, the functions of the Department of Agriculture are those of a law enforcement agency. The Department analyzes and tests economic poisons subject to the act to determine whether or not they are in violation of the provisions thereof. Its analytical and testing work is limited to official samples collected by official investigators or others who have been duly designated by the Chief of the Plant Pest Control Branch. It cannot undertake such work to help a manufacturer prepare his labeling. It is the manufacturer's responsibility to have such work carried out, which may be done by commercial laboratories or by other qualified persons. The Department is, however, willing to comment on proposed labeling submitted by manufacturers, based on available information.

The Department has no authority to recommend or to approve any specific commercial laboratory or person engaged in doing analytical

or testing work on economic poisons.

INTERPRETATION WITH RESPECT TO SHIPMENTS FOR EXPERIMENTAL USE; PERMIT REQUIREMENTS

INTERPRETATION NO. 13

(a) Shipments for Experimental Use by Certain Federal and State Agencies. The penalties provided for violation of section 3a of the act do not apply to the manufacturer or shipper of an economic poison intended only for experimental use by or under the supervision of any Federal or State agency authorized by law to conduct research in the field of economic poisons. This means that a manufacturer may freely ship economic poisons for experimental use by or under the supervision of the agencies indicated without registration or any other compliance with section 3a of the act. No Federal permits for these shipments are required.

(b) Shipments for Experimental Use by Others. In the case of shipments of economic poisons for experimental use only, to parties other than Federal or State agencies authorized by law to conduct research in the field of economic poisons or to those working under their supervision, the same exemption from the penalties set forth for violation of section 3a of the act exists: *Provided*, That a permit has been

obtained from the Department before shipment of the goods. This provision of the act is intended to apply primarily to shipments of products which have already been found to have economic poison value, but which are being tested further, usually on a larger scale, to determine their limitations. The information about their effectiveness is usually not sufficient to enable the preparation of adequate directions for use and adequate warning statements and, therefore, suitable labeling for registration cannot be prepared without further experimentation. This experimental work may be carried out on a largescale, including treatment of many acres of crops in various sections of the country. However, it must be carried out in such a way as to avoid injury to humans and useful animals. If the economic poison is to be tested for a use which is likely to result in contamination of food or feed the affected food or feed must be disposed of without allowing it to be consumed by humans, or by useful animals except those used for toxicity tests, unless there is convincing evidence that the proposed use will not result in injury to them.

(c) Sale of the Product. The economic poison may be sold to the user or may be supplied to him without charge. If it is not furnished without charge the label must bear, in addition to other required material, a statement of the names and percentages of the principal active ingredients in the product. This is intended to include the names and percentages of the ingredients commonly known as toxicants but not necessarily the names and percentages of ingredients which act primarily as solvents, emulsifiers, carriers or in a similar manner. The experimental work must be carried out by persons qualified to evaluate the results obtained. Offering the product for sale to anyone who wishes to purchase it is not considered marketing for experimental use only, and is prohibited. Products so offered will be subject to regis-

tration and all other requirements of the law.

(d) Types of Products and Labeling. (1) An economic poison shipped for experimental use may be one which has not previously been used as an economic poison, or it may be one which has had other economic poison uses and is now being tested for a new use.

(2) The labeling of all economic poisons shipped under permit must

bear the following:

(i) The prominent statement "For Experimental Use Only" on the container label and any accompanying circular or other labeling.

(ii) A warning or caution statement if it is necessary for the protection of those who may handle or be exposed to the economic poison.

(iii) The name and address of the applicant for the permit.

(iv) The name of the formulation; and,

(v) If the economic poison is to be sold, the names and percentages of its principal active ingredients.

(e) Specific and General Permits. (1) If a manufacturer desires to make a single shipment of an economic poison for experimental use,

he may obtain a permit for that specific shipment; or

(2) If he desires to make more than one shipment of a single economic poison or closely allied economic poisons for experimental use, he may apply for a general permit. A general permit will be subject to the following limitations and may be cancelled at any time for any violation of its terms:

(i) It will be good only for a specified period of time, in no case exceeding one year.

exceeding one year.

(ii) It will be subject to the truthfulness of the representations

made in the application for the permit.

(iii) It will apply only to one economic poison or closely allied group of such products. This provision is intended to include under one permit different formulations of the same material which are being tested to determine the best formulation for the particular use, but is not intended to include under one permit entirely different chemicals used as economic poisons.

(f) Application for Permits. An application for a permit for shipment for experimental use should be made in duplicate on forms which may be obtained from the Plant Pest Control Branch, Agricultural Research Service, United States Department of Agriculture, Washington 25, D. C., giving in full the following information:

(1) Name and address of the shipper and place or places from which

the shipment will be made.

(2) Proposed date of shipment or proposed shipping period not to

exceed one year.

(3) A statement of the composition of material to be covered by the permit which should apply to a single material or group of closely allied formulations of the material.

(4) A statement of the approximate quantity to be shipped.

(5) Available data or information or reference to available data or

information on the acute toxicity of the economic poison.

(6) A statement of the nature of the proposed experimental program, including the type of pests or organisms to be experimented with, the crops or animals for which the product is to be used, the areas where it is proposed to conduct the program, and including the results of previous tests where necessary to justify the quantity requested.

(7) When food or feed is likely to be contaminated, either a full statement of action which will be taken to prevent the food or feed from being consumed, except by laboratory or experimental animals, or convincing evidence that the proposed experiment will not result

in injury to man or useful animals.

(8) The percentage of the total quantity specified under subparagraph (4) of this paragraph which will be supplied without charge to the user.

(9) A statement that the economic poison is intended for experi-

mental use only.

(10) Proposed labeling for the product.

Applications will be considered as rapidly as possible. In special cases the manufacturer may request telegraphic notification at his

expense of the issuance of the permit.

(g) Limitation of Quantity of Economic Poison Permitted for Experimental Use. When the available information on the effectiveness, toxicity or other hazards inherent in a proposed experimental use of an economic poison is not sufficient to assure that it is safe under the conditions of the experiment, the full quantity requested may not be permitted or other limitations may be placed upon the permit if necessary for the protection of the public. This is intended to apply

particularly if the material is to be handled and applied by people who have not been especially trained in the use of poisons or if its use on a scale as broad as that requested is likely to constitute an unwarranted hazard.

(h) Cancellation of Permits. A permit for shipment of an economic poison for experimental use may be cancelled at any time for any violation of its terms. It may also be cancelled if it appears upon further consideration that distribution of the product under

the terms of the permit constitutes a hazard to the public.

(i) Custom Mixes. Permits will not be issued for so-called custom mixes which are ordinarily economic poisons prepared to the special formula of the user. These are not intended for experimental use, but are special economic poisons intended for special uses. When shipped in interstate commerce, they are subject to the registration and

other provisions of the law.

(j) Shipment of Products Not Classified as Economic Poisons. Section 362.17 (a) (1) provides that a product is not an economic poison when it is being put through tests in which the purpose is only to determine its value for economic poison purposes or to determine its toxicity or other properties, and when the user does not expect to receive any benefit in pest control. This will, in general, include products being put through so-called screening tests or preliminary tests to determine whether further tests with them are worth while; products shipped to toxicological laboratories to determine their toxicity; products sent to chemical laboratories for chemical investigation; and products shipped for tests by testing laboratories which maintain test plots solely to evaluate the effectiveness of the product and not for the value of the crops obtained. Permits are not required. for shipments of products of this type and they are not subject to the provisions of the act in any way. There is no requirement for any report concerning them to the Department, except when it is necessary to report the results of the tests to support claims when they are later submitted for registration or when an application for a permit for shipment for experimental use is submitted. However, confidential progress reports will be valuable to the Department.

INTERPRETATION WITH RESPECT TO LABELING OF INSECTICIDES CONTAINING BENZENE HEXACHLORIDE

INTERPRETATION NO. 14

INTERPRETATION WITH RESPECT TO LABELING OF MINERAL OIL—PYRETHRUM AND SIMILAR CONTACT HOUSEHOLD FLY SPRAYS

INTERPRETATION NO. 15

INTERPRETATION WITH RESPECT TO LABELING OF INSECTICIDES CONTAINING DDT

INTERPRETATION NO. 16

INTERPRETATION WITH RESPECT TO LABELING OF WEED KILLERS. CONTAINING 2,4-D

INTERPRETATION NO. 17

INTERPRETATION WITH RESPECT TO WARNING, CAUTION AND ANTIDOTE STATEMENTS REQUIRED TO APPEAR ON LABELS OF ECONOMIC POISONS

INTERPRETATION NO. 18

INTERPRETATION WITH RESPECT TO LABELING OF HOUSEHOLD INSECTICIDES CONTAINING CHLORDANE

INTERPRETATION NO. 19

The above interpretations are published separately and are available upon request from the Plant Pest Control Branch, Agricultural Research Service, U. S. Department of Agriculture, Washington 25, D. C.

INTERPRETATION CONCERNING NONECONOMIC POISON CLAIMS AND DIRECTIONS FOR USE, AND ECONOMIC POISONS SUBJECT TO REQUIREMENTS OF OTHER STATUTES

INTERPRETATION NO. 20

- (a) Certain products are sold for both "economic poison" and "non-economic poison" uses and the labeling of these products bears directions for use and claims which relate to both economic poison and noneconomic poison uses. For example, a product may be sold as a weed killer and also as a spray for potatoes to prevent sprouting. If such article were recommended only for use on potatoes to prevent sprouting, it would not be subject to the requirements of the act. The product, however, becomes subject to the requirements of the act by being recommended for use as an economic poison. The question has arisen concerning the extent to which the requirements of the act and regulations apply to the noneconomic poison claims and directions for use.
- (b) A product which is subject to the act as an economic poison is subject to the act in all respects. Therefore, any statement relative to the article or its ingredients, including a statement relative to the non-economic poison use of the product, which is false or misleading will result in the product being considered as misbranded under the act. Likewise, the directions for use, including directions for noneconomic poison use, must be such that no injury to the public will result if such directions are followed. For example, a product may be intended to be used as an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act and as a drug within the meaning of the Federal Food, Drug, and Cosmetic Act. If the directions for use of the product as a drug are such that injury will result to the user, the product will not be considered to be in compliance with the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act, even though the directions for use of the product as an economic poison appear to be adequate and safe.

(c) The situation may also arise where economic loss or other injury might result from either a noneconomic poison or an economic poison use of a product by virtue of the application of another statute. In the first example mentioned above, the use of the product to prevent potato sprouting might result in a residue being left in the potatoes. Furthermore, economic poisons are frequently used on or about foods other than in their production as, for example, to reduce

decay of fruits during transportation or storage, thus contaminating the food with a residue of economic poison. Even though such a residue might not be hazardous to man or other animals, it might be that it would be considered as an added poisonous or deleterious substance that is not required in the production of the food or that could be avoided by good manufacturing practice, resulting in the food being adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act. Economic loss could result to the user of the product if such a determination were made and seizure action instituted against the food. Likewise, the shipper of the food might be subject to criminal prosecution for introducing into interstate commerce a food considered to be adulterated under the Federal Food, Drug, and Cosmetic Act. However, in such a situation, the action would be contingent upon independent determination by another Federal agency; that is, an interpretation of another Federal statute would have to be made and positive action taken by another agency. Consequently, this Department could not say whether injury to the user would result if the directions for use were followed.

(d) Therefore, if the proposed usage of the economic poison conforms to good practice but results in contamination of food or feed which is, however, not injurious to human or animal health, the possibility of legal action by other administrative agencies of the Government against such food or feed, or the shipper of the food or feed, will not be taken into consideration in determining whether the economic poison, its labeling and the other material required to be submitted comply with the Federal Insectiteide, Fungicide, and Rodenti-

cide Act.

(e) The registration of an economic poison intended for use on or about food or feed is not to be construed as implying that the treated material will be in compliance with the Federal Food, Drug, and Cosmetic Act or other applicable laws.

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